K010489

APR 1 0 2001

510(k) Summary
Dyonics Vision 111 Mobile Video Unit
Date Prepared:

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

A. Submitter

Smith & Nephew, Inc.
Endoscopy Division
160 Dascomb Road
Andover, MA 01810

B. Company Contact

Steven Jackson
Manager, Regulatory Affairs
Smith & Nephew, Inc.
Endoscopy Division
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C. Device Name

Trade Name: Dyonics Vision 111 Mobile Video Unit
Common Name: Camera, Television, Endoscopic, Without Audio
Classification Name: This proposed device is classified as class II by FDA per 21 CFR 876.1500. The product codes for this device are FWF, FCW, and KQM

D. Predicate Devices

1. Dyonics Digital 3-Chip Video Camera (K972471)
2. Laparoscopy System (K914919)

E. Description of Device

The Dyonics Vision 111 Mobile Video Unit is an all in one endoscopic surgical video system containing a video camera, light source, and flat panel display. The basic methods of use and principals of operation for the Dyonics Vision 111 Mobile Video Unit are consistent irrespective of the endoscopic surgical procedure being performed. The illuminator provides light through light guide and the endoscope to illuminate the surgical site. The camera acts to capture the surgical image and transfer that image to

the flat panel display and other video recording media (i.e. video printers and video cassette recorders).

The body contact portions of the Dyonics Vision 111 Mobile Video Unit camera head will be manufactured out of Polyetheretherketone (PEEK) and polyethylene which have been used on the predicate device and various other medical devices for a verity of medical applications and have a long history of biocompatibility for human use.

The Dyonics Vision 111 Mobile Video Unit will carry a minimum Type BF electrical safety rating under UL 2601-1 (IEC 60601-1) and IEC 60601-2-18

F. Intended Use

The Smith & Nephew Dyonics 111 Mobile Video Unit is intended for use in endoscopic surgical procedures to provide illumination and visualization of articular cavities, body cavities, hollow organs and canals when used in conjunction with an appropriately indicated endoscope.

G. Comparison of Technological Characteristics

The Dyonics Vision 111 Mobile Video Unit is equivalent to previously submitted camera systems incorporating the following modifications:

The proposed Dyonics Vision 111 Mobile Video Unit incorporates the camera, light source and monitor into one portable unit. The camera will use CMOS technology to capture the video image and output it for viewing on the monitor. CMOS technology incorporates the camera and image pickup device on a single chip. This allows the camera to be placed directly in the camera head without increasing the overall size or weight, and still providing exceptional video images of surgical site.

The basic design and function of the light source and monitor remain unchanged compared to the information provided in previous submissions.

Steven Jackson

Manager, Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 0 2001

Mr. Steven Jackson
Manager, Regulatory Affairs
Smith & Nephew, Inc.
Endoscopy Division
3600 NW 138th Street
Oklahoma City, Oklahoma 73134

Re: K010489
Trade/Device Name: Dyonics Vision 111 Mobile Video Unit
Regulation Number: 876.1500
Regulatory Class: II
Product Code: GCJ
Dated: February 20, 2001
Received: February 20, 2001

Dear Mr. Jackson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number : K010489

Device Name : Dyonics Vision 111 Mobile Video Unit

Indications for Use :
The Smith & Nephew Dyonics 111 Mobile Video Unit is intended for use in endoscopic surgical procedures to provide illumination and visualization of articular cavities, body cavities, hollow organs and canals when used in conjunction with an appropriately indicated endoscope.

(PLEASE DO WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K010489